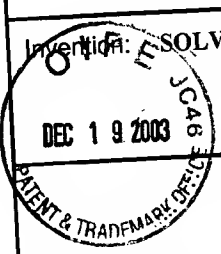


1617

Image

AMENDMENT TRANSMITTAL LETTER (Small Entity)			Docket No. 05900002AA
Applicant(s): D. Anderson			
Serial No. 09/994,937	Filing Date November 28, 2001	Examiner Bahar	Group Art Unit 1617



Invention: SOLVENT SYSTEMS FOR PHARMACEUTICAL AGENTS

TO THE COMMISSIONER FOR PATENTS:

Transmitted herewith is an amendment in the above-identified application.

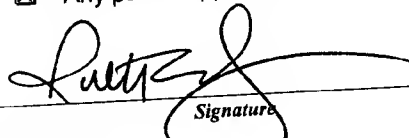
☐ Small Entity status of this application has been established under 37 CFR 1.27 by a verified statement previously submitted.

☐ A verified statement to establish Small Entity status under 37 FR 1.27 is enclosed.

The fee has been calculated and is transmitted as shown below.

CLAIMS AS AMENDED					
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST # PREV. PAID FOR	NUMBER EXTRA CLAIMS PRESENT	RATE	ADDITIONAL FEE
TOTAL CLAIMS	56	56 =	0 x	\$9.00	\$0.00
INDEP. CLAIMS	5	5 =	0 x	\$43.00	\$0.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT					\$0.00

- ☒ No additional fee is required for amendment.
- ☐ Please charge Deposit Account No. _____ in the amount of _____
- ☐ A check in the amount of _____ to cover the filing fee is enclosed.
- ☒ The Director is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-2041
- ☒ Any additional filing fees required under 37 C.F.R. 1.16.
- ☒ Any patent application processing fees under 37 CFR 1.17.



Signature

Ruth Tyler-Cross
Reg No. 45,922
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Customer number: 30743

Dated: December 19, 2003

I certify that this document and fee is being deposited on _____ with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
Signature of Person Mailing Correspondence
HAND DELIVERED
Typed or Printed Name of Person Mailing Correspondence

CC:



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of inventors Anderson

Serial No. 09/994,937

Group Art Unit: 1617

Filed: 11/28/2001

Examiner: Bahar

For: **"SOLVENT SYSTEMS FOR PHARMACEUTICAL AGENTS"**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir:

In response to the Office Action mailed on 11/19/2003, Applicant hereby elects, with traverse, a single species for each of the following genera as required by the Examiner:

- 1) Polar solvent: Water
- 2) Lipid or surfactant: Pluronic: Entry 7537 on page 1203 in the 12th edition of the Merck Index.
(e.g. Pluronic P-123, an Ethylene Oxide/Propylene Oxide Block Copolymer, also called Poloxamer 403; CAS# 9003-11-6; MW = 5,750)
- 3) Essential oil: Spearmint oil, or a component thereof
Spearmint oil: CAS #8008-79-5. Entry 6768 on page 1077 in the 12th edition of the Merck Index.
- 4) Dissolution/solubilization agent: Gentisic acid, preferably in the form of the ethanolamine salt

Gentisic acid is 2,5-dihydroxybenzoic acid, CAS#490-79-9, entry 4290 on page 688 in the 12th edition of the Merck Index.

Gentisic acid ethanolamine is the salt created by mixing equimolar amounts of gentisic acid and ethanolamine; ethanolamine is 2-aminoethanol, CAS# 141-43-5, and entry 3681 on page 588 in the 12th edition of the Merck Index.

5) Pharmaceutical active: Paclitaxel

{2aR-[2a α , 4 β , 4a β , 6 β , 9 α (α R*, β S*), 11 α , 12 α , 12a α , 12b α]}- β -(Benzoylamino)- α -hydroxybenzenepropanoic acid 6,12b-bis(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-4,11-dihydroxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester;
CAS# 33069-62-4; Entry 9049 on page 1435 in the 12th edition of the Merck Index.

The claims of the application that read on the five elected species are: 1-8, 10-13, 15-19, 27-33, 35-38, 40-44, 52-56.

Applicant notes that the independent claims of the application (claims 1, 27, 52, 53 and 54) each recite a structured fluid which comprises three elements:

- 1) a polar solvent;
- 2) a lipid or a surfactant; and
- 3) an essential oil or a dissolution/solubilization agent or both.

With reference to element #3, Applicant further notes that this element has three alternative embodiments, any one of which may be combined with elements 1 and 2. The third element may be an essential oil, in which case the structured fluid comprises a polar solvent, a lipid or a surfactant, and an essential oil. Alternatively, the third element may be a dissolution/solubilization agent, in which case the structured fluid comprises a polar solvent, a lipid or a surfactant, and a dissolution/solubilization agent. Lastly, the third element may be a combination of an essential oil and a dissolution/solubilization agent, in which case the

structured fluid comprises a polar solvent, a lipid or a surfactant, an essential oil and a dissolution/solubilization agent. Applicant notes that compliance with the Restriction Requirement has hereby been effected by electing water, a pluronic, spearmint oil, gentisic acid (e.g. ethanolamine salt), and paclitaxel. However, Applicant further notes that many alternative compounds other than those elected may be employed in the practice of the present invention. The invention is drawn to the structural fluid as a new composition of matter. As such, the invention is not limited to only a variation and the full scope of the claimed invention should be considered.

Applicant respectfully requests examination on the merits of claims of the application based on the above-listed elected species. Applicant respectfully requests allowance of the claims and issuance at the earliest possible time.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at 703-787-9400 (fax: 703-787-7557; email: ruth@wcc-ip.com) to discuss any other changes deemed necessary in a telephonic or personal interview.

Please charge any underpayment or credit any overpayment of fees to attorney's deposit account # 50-2041.

Respectfully submitted,



Ruth E. Tyler-Cross

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